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EXAMINER	
BARHAM, BETHANY P	

ART UNIT	PAPER NUMBER
1615	

NOTIFICATION DATE	DELIVERY MODE
11/17/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/510,028	RIZZOLI ET AL.	
	Examiner	Art Unit	
	BETHANY BARHAM	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 January 2009 and 23 July 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6,9,10,17,21,26 and 31-36* is/are pending in the application.

4a) Of the above claim(s) *26, 37 and 52-56* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,9,10,17,21,31-36 and 38-51* is/are rejected.

7)☒ Claim(s) *1,5,6,31,36,38-40 and 45-48* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/04/04, 10/20/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Summary

Receipt of IDS's filed on 11/04/04 and 10/20/08 is acknowledged. Claims 1-6, 9-10, 17, 21, 26, and 31-56 are pending.

Election/Restrictions

Claims 26, 37 and 52-56 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 7/23/09.
It is noted that for examination purposes Applicant has elected (a) alpha-tricalcium phosphate and (b) glycosaminoglycan with less than 99% water, a molecular weight larger than 300,000 and a weight relationship A/B of 0.2-0.5.

OBJECTIONS

The claims 1, 36, 38-40 and 46-48 are objected to because of the following informalities: they contain numerous misspellings such as "hydro-xylapatite", "flouride-apatite", "hyaluron-acid", "glycosaminoglycane", "proteoglycane", "heparine", "swellen" etc. Please correct these errors.

Claim 5 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper

dependent form, or rewrite the claim(s) in independent form. Claim 5 directed to "at least 50% of the ceramic particles have a non-spheric shape", does not further limit claim 1 which requires "the majority of the ceramic particles have a non-spheric shape".

Claim 6 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 6 directed to a pore size between 1 and 500 micrometers, does not further limit claim 1 which requires a pore size between 100 and 500 micrometers.

Claim 31 is objected to under 37 CFR 1.75(c), as being of improper dependent form, MPEP 2111.03 states "a claim which depends from a claim which "consists of" the recited elements or steps cannot add an element or step." The transitional phrase "consisting of" excludes any element, step, or ingredient not specified in the claim. *In re Gray*, 53 F.2d 520, 11 USPQ 255 (CCPA 1931); *Ex parte Davis*, 80 USPQ 448, 450 (Bd. App. 1948) ("consisting of" defined as "closing the claim to the inclusion of materials other than those recited except for impurities ordinarily associated therewith."). Applicant is required to cancel the claim(s), or rewrite the claim(s) in independent form.

Claim 45 is objected to because of the following informalities: "less that", please correct to "less than".

DOUBLE PATENTING

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 21, 31-36, and 38-39 rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3, 19-21, 27-31, and 33-34 of U.S. Patent No. US 6,733,582 ('582). Although the conflicting claims are not identical, they are not patentably distinct from each other because both claim a composition comprising a calcium phosphate particle such as alpha-tricalcium phosphate ('582 claim 3) with an overlapping a particle size of 100-250 microns ('582 claims 27-29), overlapping Ca/P ratio of 1-2 ('582 claims 33-34 (Ca/P 1-1.67)), and hyaluronic acid or hyaluronate salts, etc.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claim 21 provides for the use of the particles of "an average diameter of 100 to 250 micrometers...with those having an average diameter of 250-500 micrometers and/or together with those having an average diameter of 0.5 to 5.6 mm", but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 21 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claims 1 and 9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 claims "an average diameter of the ceramic particles is between 100-250 micrometers" and "the ceramic particles have a pore size between 100 and 500 micrometers", while claim 9 states "pore size between 340 and 450 micrometers". How is it that a particle can have a diameter of 100 microns and a pore size of 5 times the diameter (ie 500 microns)? Please clarify as this is confusing and indefinite.

Further claim 1 contains the limitation "wherein the jarring density of the ceramic particles is between 0.7g/ccm and 1.0 g/ccm". What is "jarring density"? Applicant's instant spec does not define it and a search of patent literature does not yield a definition either, in fact only Applicant's PGpub contains the phrase "jarring density". As such the limitation is not defined and confusing.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely

exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 36, recites the broad recitation polysaccharide, and the claim also recites glycosaminoglycan or alginate, which is the narrower statement of the range/limitation. Also, in the present instance, claims 41-42, and 48, recite the broad recitation "larger than…", and the claim also recites "preferably larger than", which is the narrower statement of the range/limitation.

Claim 40 recites the limitation "wherein a concentration of the ready-to-use, hydrated hydrogel or a ready-to-use, hydrated substance which can be swellen into a hydrogel" in claim 1. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-6, 17, 21, 31-36, and 38-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 0141824 (citing from equivalent patent US 6,733,582 ('582)) in view of US 5,510,418 ('418) and further in view of US 2002/0187104 ('104), US 5,290,494 ('494) and US 6,117,456 ('456).

The instant claims are directed to a kneadable and moldable bone-replacement material which consists of a mixture of: A) calcium-containing ceramic particles wherein the ceramic particles comprise a calcium- phosphate ratio having a molar Ca/P relationship between 1.0 and 2.0, wherein the calcium phosphate is selected from the following group: : Dicalcium-phosphate-dihydrate (CaHPO4 x 2 H20), dicalcium-phosphate (CaHPO4), alpha-tricalcium-phosphate (alpha-Ca3(PO4)2), beta- tricalcium-phosphate (beta-Ca3(PO4)2), calcium-deficient hydro-xylapatite (Ca9(PO4)5(HPO4)OH), hydro-xylapatite (CA10(PO4)6OH)2), carbonated apatite (Ca10(PO4)3(CO3)3(OH)2), flouride-apatite (CaI0(PO4)6(F,OH)2), chloride-apatite (CaI0 (PO4)6(C1,OH)2), whitlockite ((Ca,Mg)3(PO4)2), tetracalcium-phosphate (Ca4(PO4)20), oxyapatite (CA10(PO4)60), beta-calcium-pyrophosphate (beta-Ca2(P207), alpha-calcium- pyrophosphate, gamma-calcium-pyrophosphate, octo-calcium-phosphate (Ca8H2(PO4)6 x 5 H20), wherein at least 50% of the ceramic particles have a pore size between 100 and 500 micrometers, wherein a bulk density of the ceramic particles is between 0.6 g/ccm and 1.0 g/ccm, wherein the jarring density of the ceramic particles is between 0.7 g/ccm and 1.1 g/ccm and wherein an average diameter of the ceramic particles is between 100 and 250 micrometers; and B) a hydrogel or a substance that can be swelled into a hydrogel, and wherein: C) the

ceramic particles are of fully synthetic origin; D) the individual ceramic particles have at least a partially cohesive, porous structure; and E) the majority of the ceramic particles have a non-spheric shape.

- '582 teaches a bone replacement composition comprising particles of 0.1-100 microns of alpha-tricalcium phosphate (α-TCP) granules of 100-500 microns in size of calcium phosphates such as α-TCP (col. 3, lines 22-45; col. 4, lines 20-26), with a Ca/P ratio of 1-1.67 (abstract, col. 4, line 58-col. 5, line 3; claims 1, 3, 27-31 and 33). According to '582 the composition can additionally contain a biodegradable polymer such as hyaluronic acid or hyaluronate salts (col. 5, lines 14-15; claims 19-21). Example 4 makes a composition with TCP granules of 125-1000 microns and a solution of hyaluronic acid in the amount instant claimed in claim 40 (meeting the limitations of instant claims 1, 21, 40 and 43-45).
- '582 teaches including magnesium salts (abstract, claim 1) (meeting the limitations of instant claim 31).

'582 does not teach the particle/granule shape, density or the porosity of the calcium phosphate of instant claim 1-2, 5 and 17 or the source or molecular weight of the hyaluronic acid of claims 32-36, 38-39 and 41-48.

- '418 teaches that suitable particulate material such as TCP with a diameter of 20-250 microns can be irregular in shape (col. 13, lines 13-24) (according to the limitations of claims 1-5 and 17).

- '418 teaches that glycosaminoglycans such as hyaluronic acid are in general extracted from natural sources but that they may be synthetically produced or synthesized by microorganisms and that the composition is a polymer of
    - -(C8H13O4N)n-(C6H8O5)n-O-, where n=1 to 5000, which overlaps with the instant claimed molecular weight ranges (meeting the limitations of claims 32-36, 38-39 and 41-48).

'582 and '418 do not teach the density or the porosity of the calcium phosphate of instant claims 1 and 6.

- '104 teaches that TCP with a Ca/P ratio of 1-1.5 and a particle size of 100 microns to 1 mm are macroporous with pores of 30-200 microns in size [0017, 0024-0025] (according to the limitations of claims 1 and 6).

'582, '418, and '104 do not teach the density the calcium phosphate of instant claim 1.

- '494 teaches porous particulate resorbable TCP material with densities of 1.02 g/cm^3 and 0.6 gm/cm^3 (Example 8 and 9) (meeting the limitations of claim 1).
- According to '456, the parameters of density and porosity can be adjusted alone or in combination as require by specific applications. Slow resorption (greater than three months) is favored by the use of high density, low porosity calcium phosphate and/or rapid reaction and hardening times. Fast resorption (three or less months) is favored by the use of low density, high porosity calcium phosphate, and/or slow reaction and setting times. Guidance for adjustment of rate and completeness of reaction to form the calcium phosphate are given elsewhere herein (col. 9, lines 2-25).

- Note the specific gravity of the composition is not taught but a composition comprising granules of TCP and hyaluronic acid in the amounts and particle sizes claimed would naturally have the instant claimed specific gravity (instant claim 49).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make the composition of '582 and use the techniques of '418 to shape the particles of '582 with predictable results. A person of ordinary skill in the art would know how to substitute known density of TCP of '494 and known porosity of TCP of '104 into the specific α-TCP composition of '582 in view of '418 with predictable results. The simple substitution of a known component for another is within the purview of the skilled artisan and would yield predictable results. Furthermore, as taught by '456 the parameters of density and porosity can be adjusted alone or in combination as require by specific applications and a person of ordinary skill in the art desiring to make a bone replacement composition with fast resorption would know to use low density, high porosity calcium phosphate, specifically of '104 and '494 in the composition of '582 in view of '418 with a reasonable expectation of success. One of ordinary skill in the art would know how to optimize the ranges of '104, '494 and '456, as the MPEP 2144.05 states "Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation."

Claims 1-6, 9-10, 17, 21, 31-36, and 38-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 0141824 (citing from equivalent patent 6,733,582

('582)) in view of US 5,510,418 ('418) and further in view of US 6,210,715 ('715), US 5,290,494 ('494) and US 6,117,456 ('456).

- '582 and '418 are taught above and teaches a bone replacement composition comprising as hyaluronic acid or hyaluronate salts and particles of 0.1-100 microns of alpha-tricalcium phosphate (α-TCP) granules of 100-500 microns in size of calcium phosphates such as α-TCP (col. 3, lines 22-45; col. 4, lines 20-26), with a Ca/P ratio of 1-1.67 (abstract, col. 4, line 58-col. 5, line 3; claims 1, 3, 27-31 and 33).
- '418 teaches that suitable particulate material such as TCP with a diameter of 20-250 microns can be irregular in shape (col. 13, lines 13-24) (according to the limitations of claims 1-5 and 17).
- '418 teaches that glycosaminoglycans such as hyaluronic acid are in general extracted from natural sources but that they may be synthetically produced or synthesized by microorganisms and that the composition is a polymer of
    - -(C8H13O4N)n-(C6H8O5)n-O-, where n=1 to 5000, which overlaps with the instant claimed molecular weight ranges (meeting the limitations of claims 32-36, 38-39 and 41-48).

'582 and '418 do not teach the density or the porosity of the calcium phosphate of instant claims 1, 6, and 9-10.

- '715 teaches that microspheres of CaP (calcium phosphate) for implantation have a porosity of about 60% with a pore size of 350-500 microns (abstract, col. 9, lines 2-5) (meeting the limitations of instant claims 1, 6, 9-10).

'582, '418, and '104 do not teach the density the calcium phosphate of instant claim 1.

- '494 teaches porous particulate resorbable TCP material with densities of 1.02 g/cm^3 and 0.6 gm/cm^3 (Example 8 and 9) (meeting the limitations of claim 1).
- According to '456, the parameters of density and porosity can be adjusted alone or in combination as require by specific applications. Slow resorption (greater than three months) is favored by the use of high density, low porosity calcium phosphate and/or rapid reaction and hardening times. Fast resorption (three or less months) is favored by the use of low density, high porosity calcium phosphate, and/or slow reaction and setting times. Guidance for adjustment of rate and completeness of reaction to form the calcium phosphate are given elsewhere herein (col. 9, lines 2-25).
- Note the specific gravity of the composition is not taught but a composition comprising granules of TCP and hyaluronic acid in the amounts and particle sizes claimed would naturally have the instant claimed specific gravity (instant claim 49).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make the composition of '582 and use the techniques of '418 to shape the particles of '582 with predictable results. A person of ordinary skill in the art would know how to substitute known density of TCP of '494 and known porosity of TCP of '715 into the specific α-TCP composition of '582 in view of '418 with predictable results. The simple substitution of a known component for another is within the purview of the skilled artisan and would yield predictable results. Furthermore, as taught by '456 the

parameters of density and porosity can be adjusted alone or in combination as require by specific applications and a person of ordinary skill in the art desiring to make a bone replacement composition with fast resorption would know to use low density, high porosity calcium phosphate, specifically of '715 and '494 in the composition of '582 in view of '418 with a reasonable expectation of success. One of ordinary skill in the art would know how to optimize the ranges of '715, '494 and '456, as the MPEP 2144.05 states "Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation."

Claims 1-6, 17, 21, 31-36, and 38-51 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 2001/0053938 ('938) (as cited in Applicant's IDS) in view of US 5,510,418 ('418) and further in view of US 2002/0187104 ('104), US 5,290,494 ('494) and US 6,117,456 ('456).

- '938 teaches a paste composition for bone replacement comprising granules of 50 microns-5mm of tricalcium phosphate (TCP) and hyaluronic acid in a ratio of A/B of 0.3333 (or 1/3) (abstract, claims 1, 7-11 and 50-51).
- '938 teaches that the TCP can be porous [0024].

'938 does not teach the particle/granule shape, density or the porosity of the calcium phosphate of instant claim 1-2, 5 and 17 or the source or molecular weight of the hyaluronic acid of claims 32-36, 38-39 and 41-48.

- '418 teaches that suitable particulate material such as TCP with a diameter of 20-250 microns can be irregular in shape (col. 13, lines 13-24) (according to the limitations of claims 1-5 and 17).
- '418 teaches that glycosaminoglycans such as hyaluronic acid are in general extracted from natural sources but that they may be synthetically produced or synthesized by microorganisms and that the composition is a polymer of
    - -(C8H13O4N)n-(C6H8O5)n-O-, where n=1 to 5000, which overlaps with the instant claimed molecular weight ranges (meeting the limitations of claims 32-36, 38-39 and 41-48).

'938 and '418 do not teach the density or the porosity of the calcium phosphate of instant claims 1 and 6.

- '104 teaches that TCP with a Ca/P ratio of 1-1.5 and a particle size of 100 microns to 1 mm are macroporous with pores of 30-200 microns in size [0017, 0024-0025] (according to the limitations of claims 1 and 6).

'938, '418, and '104 do not teach the density the calcium phosphate of instant claim 1.

- '494 teaches porous particulate resorbable TCP material with densities of 1.02 g/cm^3 and 0.6 gm/cm^3 (Example 8 and 9) (meeting the limitations of claim 1).
- According to '456, the parameters of density and porosity can be adjusted alone or in combination as require by specific applications. Slow resorption (greater than three months) is favored by the use of high density, low porosity calcium phosphate and/or rapid reaction and hardening times. Fast resorption (three or less months) is favored by the use of low density, high porosity calcium

phosphate, and/or slow reaction and setting times. Guidance for adjustment of rate and completeness of reaction to form the calcium phosphate are given elsewhere herein (col. 9, lines 2-25).

- Note the specific gravity of the composition is not taught but a composition comprising granules of TCP and hyaluronic acid in the amounts and particle sizes claimed would naturally have the instant claimed specific gravity (instant claim 49).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make the composition of '582 and use the techniques of '418 to shape the particles of '938 with predictable results. A person of ordinary skill in the art would know how to substitute known density of TCP of '494 and known porosity of TCP of '104 into the specific TCP composition of '938 in view of '418 with predictable results. The simple substitution of a known component for another is within the purview of the skilled artisan and would yield predictable results. Furthermore, as taught by '456 the parameters of density and porosity can be adjusted alone or in combination as require by specific applications and a person of ordinary skill in the art desiring to make a bone replacement composition with fast resorption would know to use low density, high porosity calcium phosphate, specifically of '104 and '494 in the composition of '938 in view of '418 with a reasonable expectation of success. One of ordinary skill in the art would know how to optimize the ranges of '104, '494 and '456, as the MPEP 2144.05 states "Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation."

Claims 1-6, 9-10, 17, 21, 31-36, and 38-51 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 2001/0053938 ('938) in view of US 5,510,418 ('418) and further in view of US 6,210,715 ('715), US 5,290,494 ('494) and US 6,117,456 ('456).

- '938 and '418 are taught above and '938 teach a paste composition for bone replacement comprising granules of 50 microns-5mm of tricalcium phosphate (TCP) and hyaluronic acid in a ratio of A/B of 0.3333 (or 1/3) (abstract, claims 1, 7-11 and 50-51) and '418 teaches that suitable particulate material such as TCP with a diameter of 20-250 microns can be irregular in shape (col. 13, lines 13-24) (according to the limitations of claims 1-5 and 17).

'938 and '418 do not teach the density or the porosity of the calcium phosphate of instant claims 1, 6, and 9-10.

- '715 teaches that microspheres of CaP (calcium phosphate) for implantation have a porosity of about 60% with a pore size of 350-500 microns (abstract, col. 9, lines 2-5) (meeting the limitations of instant claims 1, 6, 9-10).

'582, '418, and '104 do not teach the density the calcium phosphate of instant claim 1.

- '494 teaches porous particulate resorbable TCP material with densities of 1.02 g/cm^3 and 0.6 gm/cm^3 (Example 8 and 9) (meeting the limitations of claim 1).
- According to '456, the parameters of density and porosity can be adjusted alone or in combination as require by specific applications. Slow resorption (greater than three months) is favored by the use of high density, low porosity calcium phosphate and/or rapid reaction and hardening times. Fast resorption (three or

less months) is favored by the use of low density, high porosity calcium phosphate, and/or slow reaction and setting times. Guidance for adjustment of rate and completeness of reaction to form the calcium phosphate are given elsewhere herein (col. 9, lines 2-25).

- Note the specific gravity of the composition is not taught but a composition comprising granules of TCP and hyaluronic acid in the amounts and particle sizes claimed would naturally have the instant claimed specific gravity (instant claim 49).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make the composition of '938 and use the techniques of '418 to shape the particles of '938 with predictable results. A person of ordinary skill in the art would know how to substitute known density of TCP of '494 and known porosity of TCP of '715 into the specific TCP composition of '938 in view of '418 with predictable results. The simple substitution of a known component for another is within the purview of the skilled artisan and would yield predictable results. Furthermore, as taught by '456 the parameters of density and porosity can be adjusted alone or in combination as require by specific applications and a person of ordinary skill in the art desiring to make a bone replacement composition with fast resorption would know to use low density, high porosity calcium phosphate, specifically of '715 and '494 in the composition of '938 in view of '418 with a reasonable expectation of success. One of ordinary skill in the art would know how to optimize the ranges of '715, '494 and '456, as the MPEP 2144.05

states "Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bethany Barham whose telephone number is (571)-272-6175. The examiner can normally be reached on Monday to Friday; 8:30 a.m. to 5:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on (571)272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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